



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2024/000356

1. M/s Heka Medicals India Pvt Ltd, VILLA NO.9,NOEL IVY CREEK,ANJIKKATH ROAD,KAKKANAD,CSEZ PO, ERNAKULAM, Kerala, India, 682037Ernakulam, Ernakulam, Kerala (India) - 682037 Telephone No.: 4844854010 FAX: 4844854010 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Heka Medicals India Pvt Ltd, No 354 B-Ground floor and C- first floor , Philip Plaza , Monippally P O , Kottayam, Kottayam, Kerala (India) - 686636 Telephone No.: 4822242217, 9895731000 FAX: 4822242217

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Respiratory Humidifier Model No.:HekaFlo - Flow rate of 2 to 60 LPM Intended Use:The HekaFlo is a medical device designed to treat spontaneously breathing patients with or without bypassed upper airways. It delivers high flow warmed and humidified respiratory gases via a breathing circuit and various patient interfaces. Based on the patient interface the flow may be set between 2- 60 Liters per minute. The device comes with three software versions, each offering additional functionalities for enhanced user experience. To achieve its intended purpose based on the selected mode, the HekaFlo utilizes a range of accessories and consumables. Class of medical device:Class B Material of construction:ABS Plastics , Silicone, Aluminum Dimension(if any):314mm x 160 mm x 220 mm Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):HekaFlo</p>

Place:

Date:13-Jun-24

State Licensing Authority